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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,835	11/25/2003	John Jackson	110129.416C1	4755

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EXAMINER	
SOROUSH, ALI	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,835	JACKSON ET AL.	
	Examiner	Art Unit	
	ALI SOROUSH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5 and 63-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5 and 63-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 04/07/2008 to the Office Action mailed on 10/05/2007 is acknowledged.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-23 and 48-51) in the reply filed on 04/07/2008 is acknowledged.

Status of the Claims

Claims 2-4 and 6-62 have been cancelled, claims 1 and 5 have been currently amended, and claims 63-93 have been newly added. Therefore claims 1, 5, and 63-93 are currently pending examination for patentability.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 5, 63-73, and 83-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rathi et al. (US Patent 6004573, Published 12/21/1999, Filed 10/03/1997) in view of Hunter et al. (US Patent 5994341, Published 11/30/1999, Filed 06/07/1995).

Applicant Claims

Applicant claims polymeric drug delivery system comprising a block copolymer having greater than 50% hydrophobic blocks and less 50% hydrophilic blocks, a water soluble polymer, and a hydrophobic drug. Wherein, the block copolymer and water soluble polymer are in a weight ratio between 30:70 to 70:30 and the drug delivery system is an injectable liquid or paste.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Rathi et al. teach, "It is the object of the present invention to provide low molecular weight triblcok copolymer drug delivery systems that are biodegradable, exhibit reverse thermal gelation behavior, namely, exist as a liquid solution at low temperatures, and provide good drug release characteristics. A further object of this invention is to provide a drug delivery system for the parenteral administration of hydrophilic and hydrophobic drugs, peptides and protein drugs, and oligonucleotides." (See column 4, Lines 56-65). "These and other objects are accomplished by means of a biodegradeable ABA type block copolymer having an average molecular weight of between about 3100 and 4500 consisting of 51 to 83% by weight of a hydrophobic A block consisting of a poly(lactide-co-glycolide) block copolymer, and about 17 to 49% by

weight of a hydrophilic B polymer block consisting of a polyethylene glycol." (See column 5, Lines 4-10). "The biodegradable, hydrophobic A-block segments are poly(α-hydroxy acids) ..." (See column 7, Lines 12-13). "Generally speaking, it is anticipated that in most instances the drug will make up between about 0.01 to about 20% by weight of the formulation with ranges of between about 0.01 to about 10% highly common." (See column 10, Lines 60-63). In a preferred embodiment Rathi et al. teach, "Paclitaxel and cyclosporine A are hydrophobic drugs that are highly insoluble in water ... The paclitaxel contained in either 20% by weight of aqueous PLGA-PEG-PLGA triblcok copolymer solutions ... or gels (i.e. above gelation temperature of the copolymer) was >85% intact after 120 days in storage (5°C. or 37°C.) ..." (See column 15, Lines 1-15).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Rathi et al. lacks a composition comprising a water soluble polymer wherein the water soluble polymer and block copolymer are in a weight ratio within the range of 30:70 and 70:30. This deficiency is cured by Hunter et al.

Hunter et al. teach in a preferred embodiment "Incorporating methoxypolyethylene glycol 350 (MePEG) into poly(E-caprolactone) to develop a formulation for controlled delivery of paclitaxel from a paste." (See column 60, Lines 13-16). "Particularly preferred polymeric carrier include ... poly(caprolactone) ..." (See column 16, Lines 55-59). "[C]ompositions may be produced: (1) as a "thermopaste" that

is applied directly to a desired site as a fluid, and hardens to a solid of the desired shape at a specified temperature (e.g. body temperature) ..." (See column 49, Lines 1-5). "For application, the syringe may be reheated to 60°C. and administered as a liquid which solidifies when cooled to body temperature." (See column 49, Lines 54-56). In the preferred embodiment Hunter et al. teach that addition of a 30:70 blend of MePEG:PCL takes more than twice as long to solidfy from fluid melt than does PCL alone. (See column 60, Lines 40-42).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Rathi et al. with Hunter et al. One would have been motivated to do so because Hunter et al. teaches that addition of MePEG to a composition comprising a polmeric carrier and paclitaxel increases the time it would take for the composition to transition from a liquid to a solid/gel once administered to the body. This will necessarily have an effect on the release rate of the drug. Therefore, if one wanted to adjust the release rate of the composition taught by Rathi et al. one could add MePEG to the composition. Therefore, the instant composition would have been obvious to one of ordinary skill in the art at the time of the instant invention.

2.. Claims 74-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rathi et al. (US Patent 6004573, Published 12/21/1999, Filed 10/03/1997) in view of Hunter et al. (US Patent 5994341, Published 11/30/1999, Filed 06/07/1995) further in view of Cha et al. (US Patent 5702717, Published 12/30/1997).

Applicant Claims

Applicant claims polymeric drug delivery system comprising a block copolymer having greater than 50% hydrophobic blocks and less 50% hydrophilic blocks, a water soluble polymer, and a hydrophobic drug. Wherein, the block copolymer and water soluble polymer are in a weight ratio between 30:70 to 70:30 and the drug delivery system is an injectable liquid or paste. Wherein, the triblock copolymer are linked by caprolactone links.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The combined teachings of Rathi et al. and Hunter et al. are discussed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

The combined teachings of Rathi et al. and Hunter et al. lack a teaching wherein the triblock copolymer are linked by caprolactone. This deficiency is cured by the teachings of Cha et al.

Cha et al. teach "The biodegradable hydrophobic, or A block, segment is preferably a poly(α-hydroxy acid) member derived from or selected from the group consisting of poly(d,l-lactide), poly(l-lactide), poly(d,l-lactide-co-glycolide), poly(l-lactide-co-glycolide), poly (ε-caprolactone), poly(γ-butyrolactone), poly(δ-valerolactone), poly (ε-caprolactone co-lactic acid), poly (ε-caprolactone-co-glycolic acid-co-lactic acid), hydroxybutyric acid, malic acid and bi- or terpolymers thereof. The above listing is not

intended to be all inclusive or necessarily self limiting as combinations or mixtures of the various α-hydroxy acids can be used to form homopolymeric or copolymeric hydrophobic block segments and still be within the scope of the invention." (See column 7, Lines 44-51). "Different poly(α-hydroxy acids) degrade at different rates. For example, the hydrophobic poly (ε-caprolactone) segment in the block copolymer degrades very slowly." (See column 10, Lines 30-32). "The degradation rate of PCL-PEG-PCL block copolymer system can be further modified by incorporating a bi- or terpolymer structure into the hydrophobic PCL segment. For example, incorporation of of glycolide and /or lactide units into the PCL segment to form a bi- or terpolymeric poly(α-hydroxy acid) segment will significantly accelerate the degradation rate of this hydrophobic block copolymer segment." (See column 10, Lines 50-57).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Rathi et al. and Hunter et al. with Cha et al. One would have been motivated to do so because Cha et al. teach that different poly(α-hydroxy acids) degrade at different rates. Therefore, if one wanted adjust the degradation rate of the composition taught by Rathi et al. one could substitute the poly(α-hydroxy acids) taught of Rathi et al. with poly(D,L-lactide-co-ε-caprolactone) taught by Cha et al. Therefore, the instant composition would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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